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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 960296.00143

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Application Number	Filed
10/761,715	01/21/2004

First Named Inventor: Mark E. Cook, et al.

Art Unit	Examiner
1644	Szperka, Michael Edward

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 61,774.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/Keith H. Heidmann/
Signature

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Typed or printed name

414-277-5753
Telephone number

12/02/2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mark E. Cook, et al.
Application No.:	10/761,715
Filing Date:	1/21/2004
Title:	*Method for Improving Body Weight Uniformity and Increasing Carcass Yield in Animals*
Atty Docket No.:	960296.00143
Examiner:	Szperka, Michael Edward
Group Art Unit:	1644

Pre-Appeal Brief Request for Review

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22323-1450

REQUEST FOR REVIEW

Applicants respectfully request consideration of the following remarks in connection with a Pre-Appeal Brief Request for Review. This paper accompanies a Notice of Appeal of the final Office Action of August 14, 2008 and is being submitted before the filing of an appeal brief.

First, the Office's assertion in the August 14, 2008 rejections that neither the rejected claims nor the patented claims of the documents cited against the rejected claims are limited to any particular dosage is clear legal error. Second, the Office's December 19, 2007 arguments supporting the present rejections, which are reiterated and quoted by the Office in the final Office Action, contain clear factual errors in the Office's interpretation of the data contained in Table 1 of the instant specification, errors that would be readily recognized by a skilled artisan. Given these clear errors and omissions, a Pre-Appeal Brief Request for Review is appropriate.

BRIEF SUMMARY OF THE INVENTION

The present invention provides a method for improving animal body weight uniformity in a target group of animals. The method comprises administering to the target group of animals an anti-phospholipase A_2 (anti-PLA_2) antibody in an amount sufficient to improve body weight uniformity in the target group of animals.

STANDING OF THE CLAIMS

In view of the Office Action of August 14, 2008, the claims stand as follows: claims 1, 5-10, 12, 25, 27, and 30-40 stand rejected under 35 U.S.C. §102(b) as being anticipated by both U.S. Patent No. 6,213,930 to Cook et al. and U.S. Patent No. 6,383,485 to Cook et al. Claims 1, 5-10, 12, 25, 27, and 30-40 also stand rejected as being unpatentable for nonstatutory obviousness type double patenting over the claims of the two cited patents. Claim 29 stands rejected under 35 U.S.C. §103(a) as being obvious over each cited patent in view of Pimentel (*Feedstuffs* 1999, 71:12-14, 18-19). Finally, Claim 29 stands rejected as

being unpatentable for nonstatutory obviousness type double patenting over the claims of the each of the two cited patents in view of Pimentel.

ARGUMENT

1. Because it was legal error to assert that neither the rejected claims nor the claims of the patent documents cited against the rejected claims are limited to any particular dosage, the rejections based on this assertion are improper.

In Applicants' Office Action response of May 13, 2008, Applicants argued that because the patents cited against the claims disclose administering a dosage of anti-PLA_2 antibody that would not be "sufficient to improve body weight uniformity," as recited in the rejected claims, the cited patents do not anticipate rejected claims 1, 5-10, 12, 25, 27, and 30-40. For the same reason, Applicants asserted that the claims of the cited patents cannot be used in an obviousness type double patenting rejection of the pending claims. See May 13, 2008 OA response, pp. 7-10, 13. In addition, Applicants argued that because the cited patents disclose administering a dosage of anti-PLA_2 antibody that is not only outside the range recited in claim 29, but is a dosage that would not work at all to increase body weight uniformity, claim 29 cannot be obvious over the cited patents in light of Pimentel and should not be subject to an obviousness type double patenting rejection over the same combination of documents. See May 13, 2008 OA response, pp. 11-13. Finally, Applicants refuted the Office's assertion that the data in Table 1 of the application's specification show that the dosage of anti-PLA_2 antibody disclosed in the cited patent documents would be "sufficient to improve body weight uniformity." See May 13, 2008 OA response, pp. 8-10. In support of these arguments, Applicants submitted with the response a declaration by Mingder Yang, an inventor in this application, containing a statistical analysis of the data presented in Table 1 of the application. See May 13, 2008 Rule 132 Affidavit.

In the final Office Action of August 14, 2008, Applicants' substantive arguments on these points and Dr. Yang's analysis in the supporting Declaration were not addressed at all. Instead, the Office summarily dismissed the arguments by stating that no dosages are recited in the rejected claims, that Applicants are arguing limitations not claimed, and that the issued claims of the cited patents also do not recite, and are thus not limited to, any specific dosage. See August 14, 2008 OA, pp. 4, 9, 11. This is clear legal error, because the rejected claims do recite specific dosages (although not a quantitative dosages in all cases), and by law the claims of the cited patents are limited to dosages reasonably supported by the patent specifications.

All the rejected claims recite a dosage. Claims 1, 5-10, 12, 25, and 27 recite administering to a target group of animals anti PLA_2 "in an amount sufficient to improve body weight uniformity." Claim 29 recites administering to a target group of animals egg yolk powder containing anti PLA_2 antibodies in a dosage of between .6 and 2.4 g anti-PLA_2 antibody yolk powder/Kg total diet. Claims 30-40 recite administering to a target group of animals anti PLA_2 "in an amount sufficient to improve body weight uniformity by at least .5 as measured by a decrease of the coefficient of variation . . ."

Claim limitations such as "effective amount" or the analogous "amount sufficient to" are considered definite limitations if the skilled artisan could determine specific dosages in light of the supporting disclosure. See discussion of the law governing such limitations at MPEP 2173.05(d)(III). Table 1 of the present application provides data from which the skilled artisan could determine the dosages of egg yolk

powder containing anti PLA_2 antibodies that would be sufficient to improve body weight uniformity (as recited in claims 1, 5-10, 12, 25, and 27) or the dosages needed to decrease in the coefficient of variation, by a specific amount (as recited in claims 30-40). Indeed, in both Declarations he submitted in this application, Dr. Yang explains how the data in Table 1 could be statistically analyzed to determine if a given dose or range of dosages would be effective at reducing body weight uniformity. Using the standard statistical methods of the skilled artisan, Dr. Yang determined from the data contained in Table 1 that neither a dosage of .5 g anti-PLA_2 antibody yolk powder/Kg total diet (see May 13, 2008 Rule 132 Affidavit) nor a dosage of $\leq$ .5 g anti-PLA_2 antibody yolk powder/Kg total diet (see April 24, 2007 Rule 132 Affidavit) would be effective at reducing body weight uniformity. Yet these are the maximum dosages disclosed in the cited patents. Thus the recited dosages are not anticipated by the cited patents.

Not only does the Office wrongly assert that the pending claims do not recite a dosage, it also wrongly asserts that the claims of the patents cited against the pending claims are not limited to any specific dosage. By law, a patented invention's acceptable range limitations are those that the skilled artisan would recognize as supported by the original disclosure. See MPEP 2163.05(III). For a more detailed discussion of this rule, the Panel is directed to Applicants' Office Action response of May 13, 2008, pages 7-8. Because the cited patents disclose only the dosage range of 0.0-0.5 g anti-PLA_2 antibody yolk powder/Kg feed (col. 4, first paragraph under "EXAMPLE" of both cited patent documents), the claims are legally limited to those dosages, and only that dosage range can be properly used in an anticipation analysis. Because the disclosed dosage range of the cited patent documents is 0.0-0.5 g anti-PLA_2 antibody yolk powder/Kg feed and such dosages would not be "sufficient to improve body weight uniformity," none of the pending claims are anticipated by the cited patent documents.

2. Because the Office misused the data in Figure 1 in a way that a skilled artisan would clearly not accept, the Office's assertion that Table 1 shows that .5 g anti-PLA_2 antibody yolk powder/Kg total diet is "sufficient to improve body weight uniformity" is factual error and an improper basis for the present rejections.

In the final Office Action of August 14, 2008, the Office did not refute Applicants' arguments in the response of May 13, 2008 that the Office improperly cherry-picked individual data points from Table 1 of the present specification to support the rejections of December 19, 2007. Indeed, the rejections were simply reiterated, and the office dismissed any discussion of dosage as irrelevant. However, this appears to be a drastic change in position, as the December 19, 2007 Office Action extensively discussed dosages and other data disclosed in Table 1 in order to support the anticipation rejections reiterated in the latest Action. Conveniently, the Office's change in position allowed it to ignore Applicants' arguments regarding the Office's misuse of the Table 1 data.

The Panel is directed to page 3 of the August 14, 2008 Office Action. The final block quote, which extends into page 4, contains the Office's December 19, 2007 assertion (using individual data points cherry-picked from Table 1) that a dosage of .5 g anti-PLA_2 antibody yolk powder/Kg feed would be "sufficient to improve body weight uniformity" and would be sufficient specifically to reduce the coefficient of variation by at least .5 or .8. Next, the Panel is directed to pages 8-10 of Applicants' response of May 13, 2008. There, Applicants explain in detail why the Table 1 data was improperly used in the Office's arguments and why the skilled artisan would never accept such use of data. Finally, the panel is directed to the two previously referenced 132 Affidavits of Dr. Yang, which explain that, when

used properly, the data of Table 1 show that in fact dosages $\leq$ .5 g anti-PLA_2 antibody yolk powder/Kg total diet are not sufficient to improve body weight uniformity, contrary to the Office's assertion. The Office never responded to this refutation, and thus a clear error of fact has been allowed to stand as a basis for the present rejections. Because the Office's anticipation rejections are based in clear error of both law and fact, Applicants respectfully request the Panel to reverse the Office's rejections of claims 1-5, 10, 12, 25, 27, and 30-40.

3. The Office's error of fact in misusing the data from Table 1 has led to the of the improper rejection of claim 29.

The Office has rejected claim 29, which recites the administration of a specific dosage of anti-PLA_2 antibody yolk powder/Kg total feed weight (.6-2.4 g), as being unpatentably obvious over each of the previously cited patent documents in view of Pimentel. The Office acknowledged that the recited dosage range is not disclosed in the patent documents (see final OA, page 6), but asserted that Pimentel discloses that higher dosages are safe, and can be used to improve health, body weight gain, and feed efficiency. However, when properly used, the data of Table 1 show that the dosages disclosed in the cited patent documents have no effect on body weight uniformity, and nothing in Pimentel would refute that conclusion. Thus the skilled artisan would have no reasonable expectation of success in increasing the dosages disclosed in the cited patents to increase body weight uniformity, and thus the obviousness rejection is improper. See MPEP 2143.02. Applicants discuss this issue in more detail on pages 11-13 of the May 13, 2008 Office Action response. Because the statutory requirements to establish a *prima facie* case of obviousness are clearly lacking in the final Office Action, Applicants respectfully request the Panel to reverse the Office's rejections of claim 29.

Conclusion

Applicants have introduced no new matter in making the above remarks. The Applicants submit that claims 1-5, 10, 12, 25, 27, and 29-40 of the present application recite patentable subject matter deserving of a timely notice of allowance. No additional fees beyond the fees authorized in the accompanying Notice of Appeal and One Month Extension of Time are believed due to enter this Pre-Appeal Brief Request for Review; however, if an additional fee(s) is/are required, please charge Deposit Account No. 17-0055 in the amount of the fee.

Respectfully submitted,
Mark E. Cook, et al.

Date: December 2, 2008

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